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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 09/472,688 | 12/27/1999 | Richard A. Shimkets Ph.D | 15966-534C-CIP1 | 9084 |

30623 7590 08/13/2003

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BOSTON, MA 02111

EXAMINER

MORAN, MARJORIE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

28

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/472,688

Applicant(s)

SHIMKETS PH.D ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 14, 46-51, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 14, 46-51, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn. Claims 1-6, 14, 46-51, and 54-55 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/03 has been entered.

Information Disclosure Statement

The information disclosure statement filed 7/31/02 has been considered in full.

35 U.S.C. 112, Written Description Rejection

Amended claim 14 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 6/6/03 have been fully considered but they are not persuasive. Applicant's arguments are addressed below.

The specification discloses SEQ ID NO: 509. A sequence consisting of SEQ ID NO: 509 meets the written description provisions of 35 USC 112, first paragraph. However, claim 14 is specifically directed to sequences that hybridize to SEQ ID NO: 509, and therefore encompasses genomic DNA, fragments of nucleic acids which may be only partially

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complementary to SEQ ID NO: 509, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), sequences "contained within" larger sequences, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. In particular, it is noted that as genomic sequences comprise introns, sequences which hybridize to SEQ ID NO: 509 may in fact bear no relationship to SEQ ID NO: 509 or any other sequence described by the instant specification, thus the genus represented by sequences which hybridize to SEQ ID NO: 509, or its complement, is not described by the instant specification.

Applicant argues in the response filed 6/6/03 that the claims have been amended to claim sequences directed specifically to SEQ ID NO: 509. In response, the examiner maintains, as set forth above, that sequences which hybridize to SEQ ID NO: 509 include a vast array of sequences not described by the instant specification. For these reasons and those previously set forth, the rejection of claim 14 is maintained.

Claim Rejections - 35 USC § 101

Claims 1-6, 14, 46-51, and 54-55 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicant's arguments filed 6/6/03 have been fully considered but they are not persuasive. Applicant again argues that sequences containing polymorphisms may be used in forensics, paternity testing, and in tracking the past migration history of modern humans. Applicant further argues that these uses are specific for a specific polymorphic sequence. Applicant argues that as SEQ ID NO: 509 is a "specific" polymorphic sequence, the uses set forth above are specific, substantial and credible with regard to SEQ ID NO: 509. In response it is noted that for any of these uses, further research would have to be performed to determine if SEQ ID NO: 509 would indeed be useful. For example, further research would have to be

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performed to determine if the polymorphic site/sequence represented by SEQ ID NO: 509 is one found in a particular subset of the population, such that its presence or absence renders meaningful (i.e. useful) information to one attempting to determine paternity or the presence of an individual at a crime site (e.g. in forensic testing). Further research would have to be performed to determine if the polymorphic sequence represented by SEQ ID NO: 509 were present in a subset of the population known to originate in a particular location, or were one known to undergo extremely rapid (or extremely slow) mutation/recombination, such that its presence or absence would render meaningful/useful information to one examining genes/mutations in migratory populations or in populations over time. Applicant is reminded that a "use" to do further research is not a specific, substantial and credible utility under 35 USC 101. As no information with regard to the presence in subsets of the population have been disclosed in the instant specification or in the prior art, the arguments with regard to utility in forensics, paternity testing, and in tracking human migratory patterns are not persuasive, and the claims are rejected.

For the reasons set forth above, the examiner maintains that the claims do not have a specific, substantial, and credible utility, or a well-established utility.

Claims 1-6, 14, 46-51, and 54-55 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Conclusion

Claims 1-6, 14, 46-51, and 54-55 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

mam
August 8, 2003

MARJORIE MORAN
PATENT EXAMINER

